Supporting Statement for Threshold of Regulation Policy
For Food-Contact Articles
0910-0298

Justification

(1) Circumstances Necessitating Information Collection

In 1958, Congress amended the Federal Food, Drug, and Cosmetic (FD&C) Act to require premarket approval of food additives (21 U.S.C. 321(s), 342(a)(2)(C), and 348). A "food additive," as defined in section 201(s) of the Act, is:

> * * * any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;***), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been shown through scientific procedures *** to be safe under the conditions of its intended use***.

To obtain the necessary premarket approval of food additives, Congress established a petition process (Section 409 of the FD&C Act) under which the safety of a new food additive is evaluated. Petitions for new food additives (21 CFR 171) must provide a basis for estimating daily dietary exposure to the additive resulting from its petitioned use. These food additive petitions must also either contain data from toxicological studies which demonstrate that the daily dietary exposure to the subject additive does not pose a safety hazard or must reference such data in FDA files. Information on the environmental impact that would result from the use and disposal of the proposed food additive must also be presented in the petition.

In November 1997, section 309 of the Food and Drug Administration Modernization Act (FDAMA) amended section 409 of the FD&C Act establishing a premarket notification process for "food contact substances". FDAMA added a definition for a "food contact substance" under section 409(h)(6) of the FD&C Act as follows:

> ***the term "food contact substance" means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food.***

Under section 409(h) of the FD&C Act, manufacturers and suppliers of food contact substances are required to notify FDA 120 days prior to marketing a food contact substance for a new use. Under section 409(h)(1), such notifications must include information on the identity and intended use of the food contact substance, the notifier?s determination that the intended use of the food contact substance is safe, all information that forms the basis for that determination, and any information that FDA requires by regulation to be provided.

Under section 409(a) of the FD&C Act (21U.S.C. 348(a)) as amended, the use of a food additive is deemed unsafe unless: (1) it conforms to an exemption for investigational use under subsection (j); (2) it conforms to the terms of a regulation prescribing its use or; (3) in the case of a food additive which meets the definition of a food contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B). However, premarket notifications for food contact substances are intended to be the primary method for authorizing the new use of food contact substances in accordance with section 409(h)(3)(A) of the FD&C act. Therefore, petitions seeking to obtain a food additive listing regulation authorizing the new use of a food additive that is also a food contact substance would not ordinarily be accepted unless the agency either agreed that a manufacturer/supplier may submit a petition or determined that the petition process was necessary to provide adequate assurance of safety.

In the Monsanto v. Kennedy decision (613 F. 2d 947 (D.C. Cir. 1979)), the U.S. Court of Appeals ruled that the FDA had considerable latitude in interpreting the phrase "may reasonably be expected to become a component of food" in the definition of a food additive (Section 201(s) of the act). In its decision, the Court stated that the Commissioner of the FDA may determine that the level of migration into food of a particular substance is so negligible as to present no public health concerns and, in such cases, may decline to define the substance as a food additive even though it comes within the strictly literal terms of the definition of a food additive. The court also stated that the Commissioner has the discretion to decline to exercise this exemption authority.

Based on the discretionary authority of the Commissioner of the FDA to exempt those substances that present no public health concerns from regulation as food additives, the agency published a final rule (Federal Register of July 17, 1995 (60 FR 36582); 21 CFR 170.39; effective date of August 16, 1995) that established a policy in 21 CFR 170.39 for determining when the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial as not to require that it be the subject of a food additive listing regulation. In other words, substances determined by the FDA to be "below the threshold of regulation" under this policy are exempt from the requirement that they be the subject of a food additive listing regulation and, therefore, do not require the submission of a food additive petition.

FDA?s threshold of regulation process in 21 CFR 170.39 would also exempt food additives that are food contact substances as defined in 409(h)(6) of the FD&C Act from the requirement that they be the subject of a food additive listing regulation in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B). However, because premarket notifications for food contact substances are intended to be the primary method for authorizing new uses of food contact substances in accordance with section 409(h)(3)(A) of the FD&C act, exemption requests submitted under 21 CFR 170.39 for the new use of a food additive that is also a food contact substance would be limited to only those cases where the agency has agreed that a manufacturer/supplier may submit such an exemption request. The main reason why the agency would continue to process a small number of exemption requests is that the threshold of regulation process offers one advantage over the premarket notification process in that the use of an ? exempted? substance is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated industry would be significantly less for food contact substances exempted under 21 CFR 170.39 in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions.

Requests for exemptions under this policy are required to contain information that enables the agency to determine if components of the food-contact article meet certain criteria as specified in 21 CFR 170.39. This is a request for an extension of OMB's approval of the information collection requirements in the following citation:

21 CFR 170.39 - Reporting

Specifies criteria that must be met to obtain an exemption from the food additive petition process for food-contact articles.

(2) How, by Whom, and for What Purpose Information Used

Requests for exemptions from the food additive listing regulation requirement are letter-type submissions from manufacturers of food packaging and food processing equipment. These submissions are reviewed by FDA personnel to ascertain if the substance(s) is adequately identified and if the proposed use meets the criteria specified in 21 CFR 170.39 for an exemption.

If the data are sufficient to support an exemption under 21 CFR 170.39, the agency informs the requestor by letter that the intended use of the substance in a food-contact article is not required to be the subject of a food additive listing regulation or a food contact notification.

(3) Consideration of Information Technology

In a **Federal Register** notice of August 31, 1994 (59 FR 45160), FDA proposed regulations that would, under certain circumstances, permit the agency to accept electronic records, electronic signatures, and handwritten signatures executed to electronic records as generally equivalent to paper records and handwritten signatures executed on paper. These proposed regulations would apply to threshold of regulation exemption requests submitted under 21 CFR 170.39.

The agency currently has a working local area network (LAN) and optical scanning system in operation. Current paper files are optically scanned and placed on the LAN. This is a preliminary step that will complement the long-range goal of electronic submission of threshold of regulation exemption requests. Guidance for electronic submission of food and color additive petitions as well as food contact notifications are currently being prepared. Submitters of threshold of regulation exemption requests will be able to use these guidance documents to help them submit exemption requests electronically.

The availability of computerized indexing services such as Med-Line and Tox-line permits requestors to search the scientific literature to determine if a component of a food-contact article has been the subject of an animal carcinogen bioassay. These data bases can also be used to determine whether any significant impurities present in the component of the food-contact article have been shown to be carcinogens in humans or animals and whether their TD_{50} values (i.e., the feeding dose that causes cancer in 50 percent of the test animals when corrected for tumors found in control animals) are below 6.25 mg/kg bodyweight/day. FDA has also instituted a computerized indexing system (SIREN: Scientific Information Retrieval and Exchange Network) to permit FDA personnel to easily locate data previously submitted to the agency.

(4) Identification of Duplication and Similar Information Already Available

A critical element in FDA's Threshold of Regulation Policy is that the use of a substance exempted by the agency is not limited to only the manufacturer who submitted the request for an exemption. Other manufacturers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. Manufacturers and other interested persons can easily access an up-to-date list of exempted substances which is on display at FDA's Dockets Management Branch and is also available on the internet at http://www.cfsan.fda.gov. A list of exempted substances can also be obtained by contacting FDA's Office of Premarket Approval (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740. This list includes the name of the company that made the request, the chemical name of the exempted substance, and the specific use for which it has been exempted, as well as any appropriate limitations. Having the list of exempted substances publicly available also decreases the likelihood that a company would submit a food additive petition or a food contact substance notification for the use of a substance for which the agency has previously granted an exemption from the food additive listing regulation requirement.

To avoid unnecessary duplication, existing data are used whenever possible by FDA in evaluating requests for exemption of components of food-contact articles under 21 CFR 170.39. This includes data in FDA files as well as data available in the scientific literature. For example, existing data in FDA files on the migration of components of food-contact articles into food or food simulating solvents can often be used to predict the level of migration resulting from similar uses of other components of food-contact articles. However, because the extent of migration of a component of a food-contact article into food depends on a number of factors (e.g., the chemical nature of the substance, the temperature of use, the type of food contacted, the length of time in contact with food, the amount of food contacted over the lifetime of a repeat-use article), and because substances used in the manufacture of food-contact articles possess a wide range of chemical and physical properties and are used under a variety of conditions, additional information is often needed to determine whether a particular use of a specific substance results in a dietary concentration that is below the "threshold of regulation".

(5) Small Businesses

FDA?s threshold of regulation process minimizes the burden on all businesses by providing a procedure that is less burdensome than the current food additive petition process. Because agency reviews made under this process require significantly less resources than petition reviews, decisions authorizing the marketing of a product are issued relatively quickly (i.e., within 4- 5 months as opposed to the 1-4 years required for the review of a petition and the issuance of a regulation). As a result, components of food-contact articles that are found to be exempt from the food additive listing regulation requirement can be marketed sooner than those authorized by the petition process. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is identical to that required under 21 CFR 170.39, the burden on industry for the preparation of a premarket notification would be similar to the burden for the preparation of a request submitted under the existing threshold of regulation process.

The agency has established the types of data necessary to demonstrate that the use of a component of a food-contact article meets the criteria for an exemption under 21 CFR 170.39. However, the agency does not have the resources to generate the data needed to support a request for an exemption under this policy. Whenever possible, assistance will be given to requestors to minimize the likelihood that unnecessary work is performed. FDA aids small businesses in dealing with the requirements through the Office of Small Manufacturers Assistance and through the scientific and administrative staffs of the agency.

Whenever possible, to reduce the burden on all businesses, FDA will provide assistance to requestors to minimize the likelihood that unnecessary work is performed. FDA's Office of Small Manufacturers Assistance will also aid small businesses in dealing with the submission requirements specified in 21 CFR 170.39. It should be emphasized that the Threshold of Regulation Policy itself is, in part, a response to representatives of the food packaging and processing industries who have proposed, both

informally and formally (Petition submitted by the Society of Plastics Industries; Docket No. 77-0122) that FDA establish a Threshold of Regulation Policy for food-contact articles.

(6) Consequences of Less Frequent Information Collection

Any restriction of the right to require certain types of data for requests submitted under this policy would significantly decrease the number of food contact substances exempted from the requirement that they be the subject of food additive petitions or food contact substance notifications. Exemptions would be restricted to those situations which involve substances which are generally recognized as safe (GRAS), substances whose use was sanctioned prior to January 1, 1958, and substances approved for investigational use under section 409(j) of the FD&C Act. All other components of food-contact articles whose use results in or which may reasonably be expected to result in migration into food, even in trivial amounts, would require premarket approval via the food additive petition process or the notification process.

(7) Special Circumstances

The submission of requests under FDA's Threshold of Regulation Policy is voluntary. Any manufacturer or supplier who submits a request would do so only one time for the specific use of a substance in a food-contact article. Additional submissions would be needed only if the requestor seeks to obtain an additional exemption for the use of the same substance under significantly different conditions. These additional submissions would be needed because the extent of migration of a component of a food-contact article into food can vary significantly depending on the conditions of use (i.e., the temperature of use, the type of food contacted, the length of time in contact with food, the amount of food contacted over the lifetime of a repeat-use article).

(8) Outside Communication

Under the Paperwork Reduction Act of 1995, Federal agencies are required to publish a notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for comment. Accordingly, FDA published a notice in the *Federal Register* of September 16, 2003 (68 FR 54232), seeking comments on the collection of information associated with its threshold of regulation process (21 CFR 170.39). No comments were received.
The paragraph below should be moved to item 12 which discusses burden.

Listed below are persons with whom FDA has consulted to obtain an estimate of the resources needed to prepare a request for an exemption of a component of a food-contact article under 21 CFR 170.39.

Name	Company	Telephone No.
Jerome Heckman	Keller and Heckman (Legal Council for the Society of Plastics Industries)	202-434-4100
Thomas Brown	Keller and Heckman	202-434-4108
Holly Foley	Keller and Heckman	202-434-4146
Clyde Takeguchi	Phoenix Regulatory Services	703-406-0906

Based on information recently provided to FDA by representatives of the food packaging and processing industries, the collection of information and preparation of an exemption request under 21 CFR 170.39 is estimated to cost anywhere from $5000 to $100,000 depending on the complexity of the project (see item 12 of this supporting document). The average time to prepare such requests is estimated to be 48 hrs. On the other hand, petitions on these types of issues can typically require anywhere from 270 to 1000 hours to prepare and cost between $35,000 and $130,000. These estimates indicate that there is a significant decrease in the overall burden to businesses for those components of food-contact articles that are exempted from regulation by the expedited process under 21 CFR 170.39 but that previously would have required premarket approval via the food additive petition process. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is identical to that required under 21 CFR
170.39, the burden on industry for the preparation of a premarket notification would be similar to the burden for the preparation of a threshold of regulation exemption request.

(9) Payment to Respondents

FDA is not proposing any payment or gift to respondents.

(10) Confidentiality of Information

Requests for exemptions of components of food-contact articles from the food additive listing regulation requirement often contain trade secret and commercial confidential information. Only information that is releasable under the Freedom of Information Regulations (21 CFR Part 20) would be released to the public. This information is also safeguarded by Section 301(j) of the FD&C Act.

A list of substances exempted under 21 CFR 170.39 is placed on display at the Dockets Management Branch and is also available on the internet at http://www.cfsan.fda.gov. This list includes the name of the company that made the request, the chemical name of the exempted substance and the specific use for which it has been exempted, as well as any appropriate limitations. It does not include any trade names or other confidential information. The agency's finding of no significant environmental impact and the evidence supporting that finding, contained in an environmental assessment, are also available for public inspection at the Dockets Management Branch.

(11) Sensitive Questions

There are no questions of a sensitive nature in the data requirements for requests for exemptions under the FDA?s Threshold of Regulation Policy.

(12) Burden and Cost to Respondents

Premarket notifications are intended to be the primary method for authorizing the new use of food contact substances in accordance with section 409(h)(3)(A) of the FD&C act. Therefore, exemption requests under 21 CFR 170.39 for the new use of a food additive that is also a food-contact substance would not ordinarily be accepted unless the agency agreed that a manufacturer/supplier may submit such an exemption request. Although FDA has typically received 60 threshold of regulation exemption requests per year over the past 5 years, the agency now estimates that up to 90% of the requests that would have previously been submitted under 21 CFR 170.39 will now be submitted under the premarket notification process for food contact substances established by section 409(h) of the FD&C Act (proposed 21 CFR Part 170, Subpart D, Premarket Notifications: see **Federal Register** of July 13, 2000; 65 FR 43269). The main advantages of the premarket notification process are that manufacturers are guaranteed a decision by FDA within 120 days of receipt of an acceptable notification and, once approved, an effective notification is exclusive to the manufacturer who submitted the request. Because the types of information needed for approval under the premarket notification process for those uses of food-contact articles involving dietary concentrations of 0.5 ppb or less is almost identical to that required under 21 CFR 170.39, the burden on industry for premarket notifications will be similar to the burden for requests submitted under the existing threshold of regulation process.

As indicated above, it is estimated that approximately 6 requests per year will be submitted under the threshold of regulation exemption process of 21 CFR 170.39. The main reason why the agency would continue to process a small number of exemption requests is that the threshold of regulation process offers one advantage over the premarket notification process in that the use of an ? exempted? substance is not limited to only the manufacturer or supplier who submitted the request for an exemption. Other manufacturers or suppliers may use exempted substances in food-contact articles as long as the conditions of use (e.g., use levels, temperature, type of food contacted, etc.) are those for which the exemption was issued. As a result, the overall burden on both the agency and the regulated

industry would be less for food contact substances exempted under 21 CFR 170.39 in that other manufacturers and suppliers would not have to prepare, and FDA would not have to review, similar submissions for identical components of food-contact articles used under identical conditions.

The calculation of the hourly burden to industry for preparing threshold of regulation exemption requests was done by soliciting information from the Society of Plastics Industries and Phoenix Regulatory Associates. Development of information required for a typical request under this policy requires a team of professional employees, which may include toxicologists, chemists, environmentalists, and lawyers. The burden of data collection would vary greatly depending on the type of request. The following examples are deemed reasonable estimates.

> Category A. A simple request that does not involve any analytical work would typically contain: (1) identity and use information; (2) a literature search of the existing toxicological data on the substance(s) to show whether or not an animal carcinogen bioassay has been carried out or whether the substance is expected to be a carcinogen or potent toxin and; (3) information on the environmental impact resulting from the proposed use of the substance. The average time to prepare such requests is estimated to be 28 hours.
>
> Category B. A complex request would include the results of analytical testing (e.g., extraction studies carried out using food-simulating solvents, analytical studies to determine the residual level of the substance(s) in the food-contact article, development of sensitive analytical methods). FDA estimates that Category B type requests will require an average time of 68 hours to prepare.

To estimate the total annual burden, the agency assumed that the 6 threshold of regulation requests received by FDA annually are equally divided between Category A and Category B types. Based on the above assumptions, the total annual burden is estimated to be 288 hours. It is assumed that each of 6 respondents will file only one request per year.

Table 1. Estimated Annual Reporting Burden[1]

21 CFR	No. of Respondents	No. of Responses per Respondent	Average Burden per Response	Total Annual Responses	Annual Burden Hours
170.39 (Categories A & B)	6	1	6	48	288

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on information provided to FDA, the annualized cost for the collection of information and preparation of a simple request (Category A) for review under the proposed Threshold of Regulation Policy would range from $5,000-$25,000 depending on the complexity of the project.
If analytical studies are required to show that the dietary exposure resulting from the proposed use is below the threshold of regulation (Category B request), FDA estimates that the additional cost would vary from $10,000 to $75,000 depending on the complexity of the project (i.e., the number of substances and food simulating solvents involved, the method of analysis). Based on these estimates, the total cost to the respondent to submit requests under FDA?s Threshold of Regulation Policy would vary from $5,000-$100,000.

(13) Other costs to respondents

The FDA has been accepting threshold of regulation requests since the August 16, 1995 effective date of the final rule establishing this policy. There are no fees required for the submission of a threshold of regulation request under 21 CFR 170.39 nor other cost burdens to respondents other than those discussed under item 12, associated with the collection of data for these submissions.

(14) Annual Cost to Government

FDA estimates that it will receive an average of 6 requests per year for review under the Threshold of Regulation Policy. An abbreviated review of the chemistry, toxicology and environmental impact information requires an average 25 hours to review.

Based on an average cost of $188,000 annually per fully supported position ($90/hr), the cost of processing a request under the Threshold of Regulation Policy would be $2250 ($90/hr x 25 hrs = $2250). Therefore, the annualized cost to the federal government is estimated to be $13,500 (i.e., $2250/request x 6 requests = $13,500)

(15) Explanation of Change to Items 13 and 14

The current estimated total annual burden of 288 hours represents a 95% decrease over the previous total annual burden of 5280 hours. The main reason for the decrease in burden is that the agency estimates that up to 90% of the requests that would have previously been submitted under 21 CFR 170.39 will now be submitted under the premarket notification process for food-contact substances established by section 409(h) of the FD&C Act (proposed 21 CFR Part 170, Subpart D, Premarket Notifications: see **Federal Register** of July 13, 2000; 65 FR 43269). The second reason for this significant decrease is that under the agency?s revised National Environmental Policy Act (NEPA) regulations (see **Federal Register** of July 29, 1997; 62 FR 40570), it is estimated that approximately 90-95% of threshold of regulation exemption requests qualify for categorical exclusions and, therefore, do not require the preparation of EAs. It is further estimated that exemption requests that qualify for categorical exclusions will require, on average, 48 hours to prepare as opposed to the 88 hours typically required to prepare exemption requests that include an EA. Therefore, the total annual burden is estimated to be 288 hours =
6 requests (Category A and B) x 48 hrs (the average burden for Category A and B requests). Prior to implementation of the premarket notification process in FY 2000 and the revised NEPA regulations, the annual industry burden associated with threshold of regulation exemption requests was estimated to be 5280 hours based on the assumption that the agency receives 60 requests per year and that each request requires on average 88 hours to prepare.

(16) Statistical Analysis, Publication Plans and Schedule

N/A

(17) Displaying of OmlB Expiration Date
N/A

(18) Exception t the Certification Statement.
N/A